the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Therma Choice™ Uterine Ballon Therapy System. Therma Choice™ Uterine Ballon Therapy System is indicated for use as a thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia (excessive uterine bleeding) due to benign causes for whom childbearing is complete. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for Therma Choice™ Uterine Ballon Therapy System (U.S. Patent Nos. 5,105,808 and 4,949,718) from Gynelab Products, Inc., and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated December 17, 1998, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Therma Choice™ Uterine Ballon Therapy System represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Therma Choice™ Uterine Ballon Therapy System is 1,031 days. Of this time, 852 days occurred during the testing phase of the regulatory review period, while 179 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: February 17, 1995. The applicant claims that the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective on November 30, 1994. However, FDA records indicate that the IDE was determined substantially complete for clinical studies to have begun on February 17, 1995, which represents the IDE effective date.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: June 17, 1997. The applicant claims June 16, 1997, as the date the premarket approval application (PMA) for Therma Choice™ Uterine Ballon Therapy System (PMA P970021) was initially submitted. However, FDA records indicate that PMA P970021 was submitted on June 17, 1997.

3. *The date the application was approved*: December 12, 1997. FDA has verified the applicant's claim that PMA P970021 was approved on December 12, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 446 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 27, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 24, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–13671 Filed 5–27–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Active Pharmaceutical Ingredient Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) in cooperation with the Association of Food and Drug Officials (AFDO) is announcing the following workshop: Active Pharmaceutical Ingredient Workshop. The workshop will address issues related to the manufacture and control of active pharmaceutical ingredients.

Date and Time: The workshop will be held on June 5, 1999, from 8 a.m. to 5 p.m. Send information regarding registration by May 27, 1999.

Location: The workshop will be held at the Adam's Mark—Riverwalk, 111 Pecan St. East, San Antonio, TX 78205, 210–354–280 or 800–444–2326. Send information regarding registration by June 1, 1999.

Contact: AFDO, P.O. Box 3425 York, PA 17402, 717–757–2888, FAX 717–755–8089, e-mail ''afdo@blazenet.net'' or see the internet address ''http://www.foodsafety.org/afdo'' for more information.

Registration: Send registration information (including name, title, firm name, address, telephone, and fax number) along with registration fee payable to AFDO (address above). The registration fee will be $199 for an AFDO member, $249 for a nonmember, and $449 for both workshop and AFDO conference. AFDO is charging these fees to cover its cost associated with the workshop and conference.

If you need special accommodations due to a disability, please contact AFDO at least 7 days in advance.

Dated: May 24, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–13559 Filed 5–27–99; 8:45 am]

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